Sugary drinks, fruit, and increased risk of gout

Dietary fructose could be a contributing factor

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The accompanying prospective cohort study by Choi and Curhan adds dietary fructose intake to the list of possible risk factors for gout.[1] Laboratory evidence that dietary fructose increases serum urate already exists, and recent epidemiological studies have found an association between dietary fructose and hyperuricaemia in the United States.[2-5]

The health professionals follow-up study was established in 1986 to examine the relation between nutritional factors and disease onset in later life in more than 50 000 American men.[1] Previous analyses have looked at the association of obesity, alcohol, and diet with the onset of gout.

This new analysis looks at the role of non-alcoholic drinks and fruit on the first onset of gout. It finds a strong association between sugar sweetened soft drinks, usually containing fructose, and gout. Consuming two servings a day of a sugar sweetened soft drink increased the risk of developing gout by 85% (relative risk 1.85, 95% confidence interval 1.08 to 3.16). This compares with an increased risk of 49% from drinking 15-29.9 g/day of alcohol, 21% from eating an extra serving of meat a day, and 95% from having a body mass index of 25.0-29.9 versus 21.0-22.9; consuming 240 ml of skimmed milk a day decreased risk by 43%.[6] A high intake of naturally occurring fructose also increased the risk of developing gout; consuming two or more glasses of fruit juice each day increased the risk by 81% (1.81, 1.12 to 2.93) and eating an apple or orange a day increased the risk by 64% (1.64, 1.05 to 2.56). These epidemiological data provide useful information for formulating appropriate dietary advice that might reduce recurrent gout.

These new data suggest that dietary fructose is an important factor in the development of gout. However, their importance for public health is context specific. In the US, soft drinks are usually sweetened with high fructose corn syrup (known in the European Union as isoglucose). In the rest of the world they are usually sweetened with sucrose—a disaccharide consisting of fructose and glucose. High fructose corn syrup is produced from corn syrups by enzymatic isomerisation. It is produced in preparations that contain 42%, 53%, and 90% of free fructose; the remainder is mainly glucose.[7]

Use of high fructose corn syrup and thus dietary intake of free fructose has increased dramatically in the US over the past 25 years.[8] It is used in soft drinks and in a variety of other manufactured foods. Concerns exist that high fructose corn syrup has had a specific effect in promoting obesity in the US, as the rise in obesity corresponds with its use.[7 8] One reason could be that fructose may have less effect on satiety than other sugars. However, some argue that because sucrose is rapidly broken down to glucose and fructose in the gut the effect of sucrose and high fructose corn syrup on obesity will be similar. An expert panel (supported by an unrestricted grant from Tate and Lyle Inc) that reviewed the evidence concluded that the "evidence is insufficient to implicate high-fructose corn syrup per se as a causal factor in the overweight and obesity problem in the United States."[7]

The findings from Choi and Curhan's study that unsweetened fruit juices and fruit increased the incidence of gout, and other recent epidemiological evidence that sweetened soft drinks increase serum urate, support the notion that free fructose intake has an adverse effect on urate metabolism.[4 5] This might in turn have a causal effect on the development of the metabolic syndrome.[3] This leads to an interesting paradox that on the one hand, fruit and fruit juices may increase serum urate—which in some studies seems to be an independent risk factor of cardiovascular disease—while on the other hand, increased fruit and vegetable intake is generally thought to reduce the risk of cardiovascular disease.[9] These data do not support a change in current advice on fruit intake, but more work is needed to understand the association between the metabolic syndrome and dietary fructose.

Global differences in the use of sweeteners in soft drinks are driven primarily by economic factors. In the US, high fructose corn syrups are cheaper than sucrose because of high tariffs on imported sugar and other measures used to support domestic sugar production.[10] The European Union has a quota for isoglucose production to protect the European sugar industry. The production quota for 2007-8 in the United Kingdom is 36 967 tonnes.[11] In the US, 7881 000 tonnes were produced in 2006-7.[12] Quotas are increasing in the EU, but the increase has levelled off in the US.[12] The case against high fructose corn syrup as a cause of obesity is not proved, but evidence suggests an adverse effect on hyperuricaemia and gout. It would be ill advised for the EU to allow increased use of isoglucose until its safety has been confirmed. Perhaps liberalisation of the sugar trade will remove the demand for high fructose corn syrup; this would improve the health of consumers and the prosperity of countries that produce cane sugar.

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Involving users in developing health services

Representation is not enough; voices must be translated into action

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Many European countries involve the public in decision making processes as part of health systems governance.[1] Moreover, the National Health Service is increasingly committed to promoting the involvement of the public in setting priorities and shaping policy and local services.[2] In the accompanying ethnographic study, Fudge and colleagues describe how user involvement, directed by policy, was implemented in the context of a local stroke modernisation programme.[3] The study suggests that professionals and service users understand and practise user involvement in different ways according to "individual ideologies, circumstances and needs," which has implications for the interpretation and implementation of policy and practice. The study is timely, given that the Department of Health wants to enhance public participation in health and social care and strengthen the onus on public bodies to consult with local communities about changes to services.[4] This will present new challenges for services.

So what is the evidence on user involvement in health care? Systematic reviews suggest that involving patients can result in new or more accessible services and prevent the withdrawal of existing provision.[5] Users can also contribute positively to services by acting as case managers, trainers, and researchers.[6] A recent Cochrane review reported gaps in the evidence to support the effectiveness of involving users, although input from users improved the clarity of patient information and patients' knowledge.[7] Interviews conducted by users also elicited more critical feedback in surveys of satisfaction than those conducted by staff.

The World Health Organization has outlined a structure of public participation based on "voice" (information provided by users on their views and experiences), "representation" (the inclusion of users on boards and committees), and "choice" (the involvement of individual patients in healthcare decisions).[1] Others describe a ladder of participation ranging from "tokenism" to approaches that give citizens control.[8] Although government policy encourages the active participation of users, the Cochrane review found no studies where users made decisions about services. Rather, users' contributions tended to be marginalised within specific roles, as data collectors or providers of information. The review highlights the need to distinguish passive forms of input (where patients' views are sought but have little potential to translate into action) from active input (where real influence and action is possible). Fudge and colleagues describe how users were involved in a range of activities aimed at improving services, although roles were restricted to particular modes of working within specific programmes.

Disabled people in particular have criticised service driven approaches that claim to devolve power but which essentially enact professional agendas.[9] Such examples are reported in Fudge and colleagues' study in relation to users' priorities for developing stroke services. When users raised transport as a priority it was disregarded by professionals as falling outside the remit of the programme.

Evidence so far raises more questions than it answers. For example, although guidelines recommend various approaches to user participation depending on the type of group (patient or public), purpose of involvement, nature of the task, and users' own preferences,[10] little evidence is available to guide these decisions.[7]

Involving users from marginalised communities can present specific challenges because they are most likely to experience health inequalities as well as unequal opportunities and unequal treatment in other areas, such as housing and employment. Fudge and colleagues show that it is possible to recruit users from a deprived area by adopting different approaches, although participation rates were low and the authors provide no information on the social demographics of the people who volunteered. They also show that ongoing effort is needed to sustain recruitment.

Wider conceptual and methodological problems exist regarding the definition of user involvement and the measurement of its effect within the context of individual programmes. Fudge and colleagues also illustrate the difficulty of assessing "effectiveness," especially when concepts are poorly defined. The question over whose outcomes or which outcomes count as indicators of success will depend on the different perspectives of the key stakeholders, and they constitute complex ethical and political decisions rather than merely technical ones.

The lack of concordance between experimental research and how complex social interventions work in practice has prompted alternative approaches to synthesising diverse sources of evidence.[11] Approaches to research which analyse the factors that contribute to the success of initiatives can enhance our understanding of how best to disseminate user involvement within organisations.[12] The ethnographic approach described by Fudge and colleagues shows that initiatives on user involvement are influenced, in part, by competing but coexisting professional ideologies informed by democratic principles versus a set of administrative procedures.

If we truly wish the public to engage in decisions about health and social care we need to distinguish between initiatives that provide opportunities for meaningful input and action and those that amount to little more than an "empty ritual."[8]

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Improving access to research data in Europe

The European Commission needs to promote access to the data whose collection it has financed

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The year 2007 marks the beginning of the European Commission's seventh framework programme for research and technological development, its main vehicle for funding research over the next seven years. It is more ambitious than its antecedent—the sixth framework programme—with a large increase in funding (63%) and the creation of a European Research Council. Health research has been boosted, having been allocated €6bn (£4.3bn; $9bn) of the overall budget of €50.5bn. Yet the seventh framework programme has done little to promote access to the data whose collection it will finance.

This lack of concrete policies on access to data in Europe contrasts with the proliferation of wider international initiatives over recent years. Such initiatives have been particularly successful in genomics and proteomics,[1] and more recently in the field of chemistry,[2] but they have also shown promise in health. Examples in the United Kingdom include the policies of the Medical Research Council and Wellcome Trust, which both require grantees to share data. In the United States, the National Institutes of Health have a similar policy—the "data sharing initiative."

The responsible sharing of health research data through open access should be encouraged for several reasons. Firstly, as a matter of principle, publicly funded research should benefit everyone, and easy access to research data represents sound stewardship of public resources.[3] Secondly, access to data facilitates the generation of new knowledge, in the form of developing alternative conceptual frameworks, testing new hypotheses, undertaking meta-analyses, and applying enhanced econometric models. Thirdly, it fosters a more critical approach to interpretation of results, which is currently perceived to be lacking in some clinical trials funded by the drug industry.[4 5] Lastly, it confronts the selective reporting of favourable results, although this problem is solved to some extent by the increasing requirement for advance registration of clinical trial protocols.

However, problems also need to be overcome. Sharing data from health research is more complex than for other types of research because of ethical and regulatory problems. For data to be meaningful, individual records should ideally be available. This would require data to be anonymised, and provision should be made to prevent reverse processing. Linking anonymised individual records to other data sets would require a complex approval system. It is unclear whether the benefits of creating a Europe wide system to facilitate this would be outweighed by the costs, given the diversity in national regulatory and data protection systems. Other legal considerations include concerns about national security, patents, royalties, embargoes on use, and ownership or intellectual property rights.[1 6-9]

A second challenge in sharing data relates to technical barriers to interoperability of computing systems and the use of different storage formats.[1 3]

Thirdly, cultural, institutional, and administrative problems, such as linguistic or managerial barriers, may exist. Furthermore, practical concerns exist for the transference of data, as exemplified by the recent loss of discs containing personal details of more than 25 million British people. Financial constraints, such as allocating costs of data management between disparate agencies, may also be a problem. Fourthly, other researchers may not be willing to use data unless their quality can be assured.[1] Finally, questions exist about the allocation of responsibility for ensuring the quality of secondary research.[10]

The many problems related to improving access to research data need not be insurmountable. Despite the absence of explicit requirements on data sharing, two important health related initiatives that are funded by the sixth framework programme and academically led—the European social survey and the survey of health, ageing and retirement in Europe—provide open access to data, free of charge. Surveys coordinated by the European Commission—specifically the survey on income and living conditions, the European core health information survey (administered by Eurostat), and Eurobarometer—also provide access to data, but users may be charged, even though these surveys are funded by European taxpayers.

The European Commission's Directorate General for Research is taking steps to improve access, with exploratory workshops on data access and earmarked funding to develop and link digital repositories and create mechanisms to preserve data.[11] Yet much more needs to be done. As major public funders of research, the framework programmes should develop policies to facilitate access to data generated by grant recipients. If framework programme 7 cannot be amended, frustratingly, the next opportunity will be framework programme 8, which is not due to begin until 2014. In the meantime, steps that the European Commission could take include developing a framework within which clear policies on access to research data can be agreed; funding and developing European data repositories; encouraging national and international public funders to develop data access policies; and supporting initiatives aimed at understanding and overcoming regulatory, technical, legal, cultural, and institutional barriers to increasing access to research data. Academically led initiatives that have made progress in sharing health related data at the European level provide examples of best practice.

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Strategies for prescribing statins

Evidence supports prescribing a standard dose without further testing or dose adjustment

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Five years ago the "fire and forget approach" was proposed as a strategy for prescribing lipid lowering drugs.[1] It involves prescribing a standard dose of statins to patients at high risk of cardiovascular disease without further testing or dose adjustment. This strategy was contrasted to the "treat to target strategy," which aims to achieve target concentrations of low density lipoprotein by titrating drugs and other measures accordingly.

Since then, several trials have shown that high dose statins in a supposed treat to target approach are more effective than the standard dose. Accordingly the United Kingdom quality and outcomes framework and the Scottish Intercollegiate Guidelines Network guideline number 97 emphasise the importance of measuring cholesterol and having targets.[2] So, is the treat to target strategy now the best option?

None of the large statin trials used the treat to target strategy suggested by most lipid experts, and none was based on the targets suggested by current guidelines.[3] They either used a fixed dose of statin throughout or made only minimal adjustments. Even the recent trials of high dose statins evaluated a fixed 80 mg dose of atorvastatin. So a mismatch exists between what was assessed in trials and what is recommended for everyday practice.

The most cited US guideline[4] requires practitioners to classify patients into three risk categories according to five factors. It recommends that practitioners should aim at different target concentrations of low

density lipoprotein depending on the patient's risk category. It is therefore not surprising that practitioners may choose to ignore these recommendations. Surveys universally show that low density lipoprotein goals are rarely met.[5] Complex strategies are also prone to producing errors. For example, statins may be withheld in people at high risk who have normal lipid concentrations, or treatment may be stopped once targets have been reached. Moreover, practitioners might be tempted to prescribe drugs like ezetimibe, which modify cholesterol concentrations but according to a recent announcement by the manufacturer have failed to show an effect even on the surrogate of intima thickness, let alone clinical outcomes.[6]

What do recent trials tell us? Two types of trial can be used to evaluate treatments—explanatory trials and pragmatic trials. Explanatory trials try to control factors that might dilute the treatment effect by having narrow inclusion criteria, participants and study centres that are highly compliant, and outcomes that are close to the assumed mechanism of treatment. Because the results of such studies tell us little about how things work in real life, pragmatic trials are also needed before treatments can be recommended. Pragmatic trials should not be seen as poor quality, and the early statin trials were clearly pragmatic in nature. The more recent ones, however, have moved towards the explanatory type. For example, people randomised to the TNT (treating to new targets) trial had to have clinically evident coronary heart disease and low density lipoprotein concentrations within a range of 3.4 mmol/l to 6.5 mmol/l during statin washout, but below 3.4 mmol/l after wash-in, when taking 10 mg of atorvastatin each day. The results may therefore not be generalisable beyond this specific group of people.[7]

While the results of such trials are hailed as proof that serum lipids are the most important causal factor for arteriosclerosis, other findings put this into perspective. All participants in the heart protection study had a simvastatin wash-in phase.[8] Benefit in the main study was independent of the pretreatment concentration of low density lipoprotein and the low density lipoprotein response to statin. A recent systematic review on statin treatment in patients with diabetes reported similar findings; this led the authors to question the treat to target approach.[9] Benefits associated with lipid concentrations should generally be interpreted with caution, because lower concentrations of low density lipoprotein may simply reflect better compliance with statins, other drugs, such as aspirin and antihypertensives, or lifestyle changes, and may not be the result of statin dose titration.[10]

According to the TNT trial, 50 people as specified above would have to be treated for five years to prevent one event. This benefit may not be reaped unless eligible people have been identified and had their blood lipids checked regularly. In other words, benefit can only come from rigorously implementing the treat to target approach. In everyday practice the benefit from the TNT trial would be diluted considerably. Alternatively, the fire and forget strategy is supported by many high quality clinical trials, such as the 4S trial.[11] None of these trials made treat to target dose adjustments. Therefore, the treat to target strategy still has to be tested in a pragmatic trial. Whether funding for such a trial will ever be available remains to be seen.

Another question is whether we should force single risk factors, such as high cholesterol, to very low values with very high doses of statins as the treat to target approach suggests. As doses of statins are increased the returns get smaller,[12] whereas side effects continue to rise in a linear fashion.[13] A more effective approach might be to modify several risk factors with a cocktail of various preventive drugs that do not need dose adjustments.[14]

Despite the results of recent high dose statin trials, it is unclear whether possible benefit really translates into clinical practice. All we can say is that everyone at high risk of cardiovascular complications should be offered a standard dose of statin. Anyone with manifest disease would be eligible, irrespective of their initial cholesterol concentration. Only once we have achieved this should we think of further refinements.

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Malnutrition in hospitals

Still common because screening tools are underused and poorly enforced

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Malnutrition is a common cause and consequence of illness, particularly in older people. The number of malnourished people leaving NHS hospitals in England has risen by 85% over the past 10 years. It is still rising and reached almost 140 000 in 2006-7.[1] Surveys elsewhere consistently find that about 20% of patients in general hospitals are malnourished (body mass index < 18.5 (the World Health Organization 1995 cut off for malnutrition), or thin and losing weight, or both). Figures are higher if specific nutrient deficiencies or functional indications of malnutrition are included.

Despite the frequency of malnutrition, it is undiagnosed in up to 70% of patients. This is partly because of the lack of simple laboratory tests, and because biochemical tests for nutritional status are difficult to interpret, particularly as they are often influenced by acute phase responses to inflammation in sick patients. Around 70-80% of malnourished patients currently enter and leave hospital without action being taken to treat their malnutrition and without the diagnosis appearing on their discharge summary.[2 3]

Malnutrition affects the function and recovery of every organ system, increases the risk of infection, extends hospital stay, and makes readmission more likely. Clinicians need to be able to identify patients who have malnutrition or are at risk of malnutrition and then to refer them to dietitians or multidisciplinary nutrition support teams as appropriate, as this can greatly improve outcomes.

So how can this be achieved? In 2003, the British Association for Parenteral and Enteral Nutrition developed the "malnutrition universal screening tool"—a simple score chart that allows health professionals to identify and refer adults at risk of malnutrition. It has a high sensitivity and specificity.[4] Other similar scoring systems exist, but they need to be validated before use in community and hospital settings.[5]

We still await an enforceable requirement to administer a validated screening tool, but nutritional scoring is now required to achieve clinical standards for patients in hospital.[6 7] The National Institute for Health and Clinical Excellence recommended in 2006 that all patients in hospital should be screened and monitored regularly for malnutrition.[8] However, these standards are weakly policed and are probably insufficient to stop many elderly people becoming malnourished if the quality of food is poor and there is a lack of staff to feed people.[9]

Nutritional support is an important part of medical treatment and—in relation to withholding or failing to offer it—is treated in law as equal to drugs.[10] Nevertheless, hospital food is still provided by caterers who lack validated training in nutrition. Most hospitals have no designated medical posts to oversee the complex scientific matters that underpin both artificial feeding and "normal" food provision. Malnutrition is also often overlooked in residential care homes from which many patients come, even though the Care Commission for Scotland recommends that a malnutrition universal screening tool should be included in the registration process when patients are first admitted to a residential home.[11]

The final solution to malnutrition in hospitals probably lies in recognising human nutrition as a discrete discipline, in which all medical graduates should reach a minimum level of competence, and some will specialise. The General Medical Council recognises the need for a basic understanding of human nutrition. Its publication *Tomorrow's Doctor* states, "They must know about and understand the role that lifestyle, including diet and nutrition, can play in promoting health and preventing disease."[12] This is now the responsibility of deans and curriculum committees. In 1999, supported by the Department of Health and Rank Prize Funds, the intercollegiate group on nutrition—now a formal subgroup of the Academy of Medical Royal Colleges—established the intercollegiate course on human nutrition. It runs two or three times a year to provide a multidisciplinary integrated understanding of the principles of human nutrition as a minimal experience to promote safety and competence to practise. Its learning objectives and content are currently under review in relation to the changing demands of training during the foundation years. Attending the course is a necessity for the diploma in nutrition of the Royal College of Paediatrics and Child Health, and an informal requirement for higher training in gastroenterology and metabolic medicine. A strong case can be made for this course being an approvable option within training for other medical specialties, such as cardiology, diabetes, and public health.

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